May 31, 2002

Mr. Bryan Sheets
Eli Lilly and Company
P. O. Box 99
Clinton, IN 47842

Re: **165-15691-00009**
Minor Source Modification to:
Pending Part 70 permit No.: **T165-6462-00009**

Dear Mr. Sheets:

Eli Lilly and Company has a pending Part 70 operating permit (T165-6462-00009, submitted on August 21, 1996). An application to modify the source was received on March 8, 2002. Pursuant to 326 IAC 2-7-10.5 the following is approved for construction and operation at the source:

The replacement of the dryer bucket of existing rotary vacuum dryer RVD5, located in Building C13A.

The following construction conditions are applicable to the proposed project:

General Construction Conditions

1. The data and information supplied with the application shall be considered part of this source modification approval. Prior to any proposed change in construction which may affect the potential to emit (PTE) of the proposed project, the change must be approved by the Office of Air Quality (OAQ).

2. This approval to construct does not relieve the permittee of the responsibility to comply with the provisions of the Indiana Environmental Management Law (IC 13-11 through 13-20; 13-22 through 13-25; and 13-30), the Air Pollution Control Law (IC 13-17) and the rules promulgated thereunder, as well as other applicable local, state, and federal requirements.

3. Effective Date of the Permit
Pursuant to IC 13-15-5-3, this approval becomes effective upon its issuance.

4. Pursuant to 326 IAC 2-1.1-9 and 326 IAC 2-7-10.5(i), the Commissioner may revoke this approval if construction is not commenced within eighteen (18) months after receipt of this approval or if construction is suspended for a continuous period of one (1) year or more.

5. All requirements and conditions of this construction approval shall remain in effect unless modified in a manner consistent with procedures established pursuant to 326 IAC 2.

6. Pursuant to 326 IAC 2-7-10.5(l)(3), the emission units constructed under this approval shall be deemed incorporated in the Part 70 permit application and will be included in the Part 70 permit when issued.

The source shall comply with the requirements of this modification and all existing applicable requirements specified in the existing source permits.

This decision is subject to the Indiana Administrative Orders and Procedures Act - IC 4-21.5-3-5. If you have any questions on this matter call (800) 451-6027, press 0 and ask for Scott Fulton or extension (3-5691), or dial (317) 233-5691.

Sincerely,

Original signed by Paul Dubenetzky

Paul Dubenetzky, Chief
Permits Branch
Office of Air Quality

Attachments
SDF
cc: File - Vermillion County
Vermillion County Health Department
Air Compliance Section Inspector - Jim Thorpe
Compliance Data Section - Karen Nowak
Administrative and Development - Janet Mobley
Technical Support and Modeling - Michele Boner

Indiana Department of Environmental Management
Office of Air Quality

Technical Support Document (TSD) for a
Minor Source Modification to a Pending Part 70 Permit

Source Background and Description

Source Name:	Eli Lilly and Company - Clinton Labs
Source Location:	10500 South State Road 63, Clinton, Indiana 47842
County:	Vermillion
SIC Code:	2833
Part 70 Permit No.:	165-6462-00009
Part 70 Issuance Date:	Pending
Minor Source Modification No.:	165-15691-00009
Permit Reviewer:	SDF

The Office of Air Quality (OAQ) has reviewed a Minor Source Modification application from Eli Lilly and Company relating to the replacement of the dryer bucket of existing rotary vacuum dryer RVD5, located in Building C13A.

Request

On March 8, 2002, Eli Lilly and Company submitted an application to replace the dryer bucket of rotary vacuum dryer RVD5, located in Building C13A.

Pursuant to 326 IAC 2-7-10.5(b), the owner or operator of a source may repair or replace an emission unit or air pollution control equipment or components thereof without New Source Review (NSR) if the repair or replacement:

(1) results in a potential to emit for each regulated pollutant that is less than or equal to the potential to emit of the equipment or the affected emissions unit that was repaired or replaced,

(2) is not a major modification under 326 IAC 2-2, 326 IAC 2-3, or 326 IAC 2-4.1, and

(3) returns the emissions unit, process, or control equipment to normal operation after an upset, malfunction, or mechanical failure or prevents impending and imminent failure of the emissions unit, process, or control equipment.

In addition, if the repair or replacement qualifies as a reconstruction or is a complete replacement of an emissions unit or air pollution control equipment and would require a modification approval or operating permit revision under a provision of this rule, the owner or operator of the source must submit an application no later than thirty (30) calendar days after initiating the repair or replacement.

The potential to emit of the proposed vacuum dryer will be equal to or less than the existing vacuum dryer, the modification is not a major modification under 326 IAC 2-2, 326 IAC 2-3, or 326 IAC 2-4.1, the replacement prevents impending and imminent failure of the emissions unit and process, and the replacement is considered a replacement of the entire unit.

Therefore, pursuant to 326 IAC 2-7-10.5(b), the owner or operator may replace the dryer bucket prior to receiving the appropriate new source review (NSR) approval.

The Office of Air Quality (OAQ) has determined that the proposed replacement shall be treated as installation of a new emissions unit for the purposes of new source review. The proposed project does not constitute reconstruction of a process or production unit because:

(a) the fabrication, erection, or installation covered by this application does not constitute a collection of all equipment necessary to the production of an intermediate or final product, and
(b) the fixed capital cost of this project does not exceed 50% of the fixed capital cost for replacement of any affected process or production unit.

The unrestricted potential to emit (UPTE) from the rotary vacuum dryer is determined to be 179.58 tons methylene chloride per year. Methylene chloride is a regulated hazardous air pollutant (HAP). After application of emission controls, the methylene chloride emissions are estimated to be 12.39 tons per year.

Pursuant to 326 IAC 2-7-10.5(d)(6), a modification that is subject to a reasonably available control technology (RACT), a new source performance standard (NSPS), or a national emission standard for hazardous air pollutant (NESHAP) and the RACT, NSPS, or NESHAP is the most stringent applicable requirement, except for those modifications that would be subject to the provisions of 40 CFR 63, Subpart B, the proposed modification may be permitted via a minor source modification.

Since the most stringent standard applicable to the vacuum dryer is the National Emission Standard for Hazardous Air Pollutants (NESHAP), 40 CFR 63, Subpart GGG, and the proposed modification is not subject to the provisions of 40 CFR 63, Subpart B, the proposed modification shall be approved as a Minor Source Modification pursuant to 326 IAC 2-7-10.5(d)(6).

No permit modification shall be issued because the source operating permit is pending.

Existing Approvals

The source submitted their Title V permit application on August 21, 1996. This permit is currently pending. Since submittal of their Part 70 permit application, the source has submitted or obtained the following:

(a)	First Significant Source Modification:	165-12309-00009	Issued January 16, 2001
(b)	First Administrative Amendment:	165-14056-00009	Issued April 25, 2001
(c)	Second Administrative Amendment:	165-14508-00009	Pending
(d)	Third Administrative Amendment:	165-14531-00009	Pending

Enforcement Issue

There are no enforcement actions pending.

Recommendation

The staff recommends to the Commissioner that the Minor Source Modification be approved. This recommendation is based on the following facts and conditions:

Unless otherwise stated, information used in this review was derived from the application.

Emission Calculations

The proposed vacuum dryer will generate the hazardous air pollutant (HAP) methylene chloride.

(a) Unrestricted Potential to Emit (UPTE):

The following calculations determine the methylene chloride UPTE based on the maximum hourly emissions rate of 41 pounds per hour, emissions before controls, and 8760 hours of operation.

41 lb methylene chloride/hr * 8760 hr/yr * 1/2000 tons/lb = **179.58 tons methylene chloride/yr**

(b) Emissions After Controls:

The following calculations determine the emissions after controls from the proposed modification based on the estimated emissions before controls, and a control efficiency of 93.1% as required in CP 165-9135.

179.58 tons methylene chloride/yr * (1 - 0.931) = **12.39 tons methylene chloride/yr**

Potential To Emit

Pursuant to 326 IAC 2-1.1-1(16), Potential to Emit is defined as "the maximum capacity of a stationary source to emit any air pollutant under its physical and operational design. Any physical or operational limitation on the capacity of a source to emit an air pollutant, including air pollution control equipment and restrictions on hours of operation or type or amount of material combusted, stored, or processed shall be treated as part of its design if the limitation is enforceable by the U.S. EPA."

This table reflects the PTE before controls due to the modification. Control equipment is not considered federally enforceable until it has been required in a federally enforceable permit.

Pollutant	Potential To Emit (tons/year)
PM	0.00
PM-10	0.00
SO_2	0.00
VOC	0.00
CO	0.00
NO_x	0.00

Note: For the purpose of determining Title V applicability for particulates, PM-10, not PM, is the regulated pollutant in consideration.

Pollutant	Potential To Emit (tons/year)
Methylene Chloride	179.58
Total Combined HAPs	179.58

Since the most stringent standard applicable to the vacuum dryer is the National Emission Standard for Hazardous Air Pollutants (NESHAP), 40 CFR 63, Subpart GGG, and the proposed modification is not subject to the provisions of 40 CFR 63, Subpart B, the proposed modification shall be approved as a Minor Source Modification pursuant to 326 IAC 2-7-10.5(d)(6).

County Attainment Status

The source is located in Vermillion County.

Pollutant	Status
PM_{10}	maintenance attainment
SO_2	attainment or unclassifiable
NO_2	attainment or unclassifiable
Ozone	attainment or unclassifiable
CO	attainment or unclassifiable
Lead	attainment or unclassifiable

(a) Volatile organic compounds (VOC) are precursors for the formation of ozone. Therefore, the VOC emissions are considered when evaluating the rule applicability relating to the ozone standards. Vermillion County has been designated as attainment or unclassifiable for ozone. Therefore, the VOC emissions were reviewed pursuant to the requirements for Prevention of Significant Deterioration, 326 IAC 2-2 and 40 CFR 52.21.

(b) Vermillion County has been classified as maintenance attainment for PM10 and attainment or unclassifiable for all other criteria pollutants. Therefore, these emissions were reviewed pursuant to the requirements for Prevention of Significant Deterioration (PSD), 326 IAC 2-2 and 40 CFR 52.21.

Source Status

Existing Source Definition (emissions after controls, based upon 8760 hours of operation per year at rated capacity and/or as otherwise limited):

Unit	PM (tons/yr)	PM10 (tons/yr)	SO2 (tons/yr)	NOx (tons/yr)	VOC (tons/yr)	CO (tons/yr)	Worst Case Single HAP (tons/yr)	Comb. HAPs (tons/yr)
Existing Source	NAv*	NAv*	NAv*	NAv*	>100	NAv*	NAv*	NAv*

PSD Levels	250	250	250	250	250	250	-	-
Part 70 Levels	-	100	100	100	100	100	10	25

* NAv = not available

(a) The existing source emission data is obtained from First Significant Source Modification 165-12309-00009, completed by Dr. Trip Sinha, issued on January 16, 2001.

(b) The existing source is a major stationary source because it is in one of the 28 listed source categories and at least one regulated pollutant is emitted at a rate of 100 tons per year or more.

(c) The existing source is a Title V major stationary source because the VOC potential to emit (PTE) exceeds the applicable level of 100 tons/yr.

Source After the Proposed Modification

Source Definition, After the Proposed Modification (emissions after controls, based upon 8760 hours of operation per year at rated capacity and/or as otherwise limited):

Unit	PM (tons/yr)	PM10 (tons/yr)	SO2 (tons/yr)	NOx (tons/yr)	VOC (tons/yr)	CO (tons/yr)	Worst Case Single HAP (tons/yr)	Comb. HAPs (tons/yr)
Existing Source	NAv*	NAv*	NAv*	NAv*	>100	NAv*	NAv*	NAv*

PSD Levels	250	250	250	250	250	250	-	-
Part 70 Levels	-	100	100	100	100	100	10	25

* NAv = not available

(a) The source after the proposed modification is still a major stationary source because it is still in one of the 28 listed source categories and at least one regulated pollutant is still emitted at a rate of 100 tons per year or more.

(b) The source after the proposed modification is still a Title V major stationary source because the VOC potential to emit (PTE) still exceeds the applicable level of 100 tons/yr.

Federal Rule Applicability

New Source Performance Standards (NSPS):

There are no New Source Performance Standards (NSPS) that apply to the proposed vessel.

National Emission Standards for Hazardous Air Pollutants (NESHAPs):

40 CFR 63, Subpart GGG:

Because Clinton Laboratories is a major source of HAP emissions and produces pharmaceutical products, the source is subject to the requirements of the NESHAP for pharmaceutical production (40 CFR 63, Subpart GGG). The proposed replacement will not change the requirements of this rule.

40 CFR 63, Subpart B:

The provisions of Section 112(g) of the Clean Air Act Amendments of 1990, as implemented via CFR Part 63, Subpart B and 326 IAC 2-4.1, do not apply to this project because:

(a) the equipment in this project is regulated under the Nation Emission Standards for Hazardous Air Pollutants (NESHAP) for Pharmaceutical Production, 40 CFR Part 63, Subpart GGG, which were promulgated on September 21, 1998. The equipment will be subject to the existing source MACT requirements of that rule, and

(b) this proposed project does not constitute construction or reconstruction of a process or production unit because:

(1) the fabrication, erection, or installation covered by this application does not constitute a collection of all equipment necessary to the production of an intermediate or final product,

and

(2) the fixed capital cost of this project does not exceed 50% of the fixed capital cost for replacement of any affected process or production unit.

40 CFR 63, Subpart H:

Because dryer RVD-5 handles methylene chloride, it is subject to the NESHAP for hazardous organic equipment leaks (40 CFR 63, Subpart H). The proposed replacement will not change the requirements of this rule.

State Rule Applicability

Entire State Rule Applicability:

326 IAC 1-6-3 (Preventive Maintenance Plan):

The proposed source is required to have a preventive maintenance plan for the emission units and control devices of the source.

326 IAC 2-4.1 (HAP Major Sources)

Pursuant to 326 IAC 2-4.1-1(b), this rule does not apply if the source is a major source regulated by a standard issued pursuant to Section 112(d) of the Clean Air Act.

This source, including the proposed vessel is a major source regulated by 40 CFR 63, Subpart GGG, a standard issued pursuant to Section 112(d). Thus, 326 IAC 2-4.1 does not apply.

326 IAC 2-6 (Emission Reporting)

This source is subject to 326 IAC 2-6 (Emission Reporting), because the source VOC emissions exceed the applicable level of 100 tons per year.

Individual State Rule Applicability

There are no individual state rule that apply to the proposed vessel.

Permit Changes

No changes to any permit are necessary as a result of the proposed modification.

Conclusion

The proposed vacuum dryer shall be constructed and operated pursuant to attached minor source modification 165-15691-00009 and all other applicable existing permits.